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July 25, 2006

INFORMATION DISCLOSURE STATEMENT  
Examining Group *Not yet assigned*  
Patent Application  
Docket No. SPO-124  
Serial No. 10/561,022

David Saliwanchik  
David R. Saliwanchik, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : *Not yet assigned*  
Art Unit : *Not yet assigned*  
Applicant(s) : Saito *et al.*  
Serial No. : 10/561,022  
Filed : December 16, 2005  
Conf. No. : *Not yet assigned*  
For : Use of Toll-Like Receptor-Expressing Cells

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.97 AND 1.98

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. Copies of the cited documents are enclosed. However, the applicants have not submitted a copy of the published U.S. patent application cited on attached Form PTO/SB/08 pursuant to 37 CFR 1.98(a)(2)(ii). Also enclosed, is a copy of an English translation of the abstract, claims, and detailed description of the Japanese patent 2002-034565. Note that the WO 02/06482 is a corresponding application to JP 2002-034565. Since the references Kitazawa *et al.* and Shimosato *et al.* are not in English, translations of the abstracts have been submitted.

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO/SB/08 with initials or other appropriate

marks. If any additional fee is required, or to credit any overpayment, please use Deposit Account No. 19-0065.

Applicants respectfully assert that the substantive provisions of 37 C.F.R. §§ 1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,



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DRS/wrc

Enclosures: Form PTO/SB/08 (2 pages)  
References listed therein (12)  
International Search Report  
Written Opinion



PTO/SB/08A (07-05)  
Approved for use through 07/31/2006.

**Complete if Known**

Substitute for form ~~1-464-00~~ TO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

2

Application Number	10/561,022
Filing Date	December 16, 2005
First Named Inventor	Tadao Saito
Art Unit	not yet assigned
Examiner Name	not yet assigned

Attorney Docket Number

SPO-124

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
U1		US-2003/0124655 A1	07-03-2003	Akira et al.	All
U2		US-			
U3		US-			
U4		US-			
U5		US-			
U6		US-			
U7		US-			
U8		US-			
U9		US-			
U10		US-			
U11		US-			
U12		US-			
U13		US-			

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
F1		EP 1 302 541 A1	04-16-2003	Akira et al.	All	
F2		JP 2002-034565 A	02-05-2002	Akira et al.	All	x
F3		WO 02/06482 A1	01-24-2002	Akira et al.	All	
F4						
F5						
F6						
F7						

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
Sheet	2	of	2	Application Number	10/561,022
				Filing Date	December 16, 2005
				First Named Inventor	Tadao Saito
				Art Unit	not yet assigned
				Examiner Name	not yet assigned
				Attorney Docket Number	SPO-124

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	R1	BAUER, M. et al., "Bacterial CpG-DNA Triggers Activation and Maturation of Human CD11c <sup>+</sup> , CD123 <sup>+</sup> Dendritic Cell," <i>The Journal of Immunology</i> , 2001, pp. 5000-5007, Vol. 166.		T <sup>2</sup>
	R2	HEMMI, H. et al., "A Toll-like receptor recognizes bacterial DNA," <i>Nature</i> , 2000, pp. 740-745, Vol. 408, No. 6813.		
	R3	IMAEDA, H. et al., "In vivo response of neutrophils and epithelial cells to lipopolysaccharide injected into the monkey ileum," <i>Histochem. Cell Biol.</i> , 2002, pp. 381-388, Vol. 118, No. 5.		
	R4	KITAZAWA, H. et al. "Cloning sTLR1 and 6 that interact with swine Toll-like receptor (sTLR)2 and their expression analysis," <i>The Annual Meeting of the Japan Society for Bioscience, Biotechnology, and Agrochemistry</i> , April 2003, 2A04a07, Vol. 1.		x
	R5	KLINMAN, D.M. et al. "CpG DNA: recognition by and activation of monocytes," <i>Microbes and Infection</i> , 2002, pp. 897-901, Vol. 4.		
	R6	SHIMOSATO, T. et al. "Cloning Swine Toll-like receptor (sTLR)2 and its expression analysis," <i>The Annual Meeting of the Japan Society for Bioscience, Biotechnology, and Agrochemistry</i> , April 2003, 2A04a06, Vol. 1.		x
	R7	TAKESHITA, F. et al., "Role of Toll-Like Receptor 9 in CpG DNA-Induced Activation of Human Cells," <i>The Journal of Immunology</i> , 2001, pp. 3555-3558, Vol. 167.		
	R8	TAKEUCHI, O. et al. "Toll-like receptors; their physiological role and signal transduction system," <i>International Immunopharmacology</i> , 2001, pp. 625-635, Vol. 1.		
	R9	YOSHIMURA, A. et al. "Structural requirements of muramylpeptides for induction of Toll-like receptor 2-mediated NF-κB activation in CHO cells," <i>J. Endotoxin Res.</i> , 2000, pp. 407-410, Vol. 6, No. 5.		
	R10			

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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U.S. Patent Application No.:10/561,022  
Your Ref.:SPO-124  
Our Ref.:M1-X0301P-US

## LIST OF REFERENCES

	Author	Reference
1 *1	Akira S, et al	WO 02/06482, A1;2002.1.24
2 *2	Akira S, et al	JP 2002-34565, A;2002.2.5
3 *1	Bauer M, et al	J Immunol. 2001 Apr 15;166(8):5000-7
4 *1	Hemmi H, et al	Nature. 2000 Dec 7;408(6813):740-5
5 *1	Imaeda H, et al	Histochem Cell Biol. 2002 Nov;118(5):381-8
6 *3	Kitazawa H, et al	the Annual Meeting of the Japan Society for Bioscience, Biotechnology, and Agrochemistry;2003.4.1:2A04a07
7	Klinman DM, et al	Microbes Infect. 2002 Jul;4(9):897-901
8 *3	Shimosato T, et al	the Annual Meeting of the Japan Society for Bioscience, Biotechnology, and Agrochemistry;2003.4.1:2A04a06
9 *1	Takeshita F, et al	J Immunol. 2001 Oct 1;167(7):3555-8
10	Takeuchi O, et al	Int Immunopharmacol. 2001 Apr;1(4):625-35
11	Yoshimura A, et al	J Endotoxin Res. 2000;6(5):407-10

\*1  
Nos. 1, 3 to 5 and 9: Copies of these references are not provided since they were cited in the International Search Report, and as such, should have been provided directly by the WIPO under the exchange program between the USPTO, the EPO and the JPO. Please submit the ISR as a concise Explanation of Relevance, since reference No. 1 is not in English. Furthermore, they were also cited in the Written Opinion.

\*2  
No. 2: Please submit an English translation of the abstract, claims and detailed description of the enclosed reference, since this reference is not in English. (Please note that the claims and detailed description are computer translations.)

\*3  
Nos. 6 and 8: Since these references are not in English, please submit the enclosed English translations of the abstracts.